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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/698,493 10/27/00 ANDERSON

B LN. 01304

SUSANNE M. HOPKINS, ESQ.
LIFENET
5809 WARD COURT
VIRGINIA BEACH VA 23455

QM12/1003

EXAMINER

FRIDDY, M

ART UNIT

PAPER NUMBER

3732

DATE MAILED:

10/03/01

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/698,493

Applicant(s)

Anderson et al.

Examiner

Michael Priddy

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 27, 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-139 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Oct 27, 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Drawing

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pins located parallel to the interface of adjacent bone portions as recited by claim 131 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 124, 125, 126/125, 127/126/125 and 131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 124 and 125 each require the bone graft to have a diameter. It is unclear how the graft can have a diameter if it also has widths and heights.

B) Claim 131 requires the cortical pins to be parallel to the interfaces of adjacent bone portions. Claim 130 has already established that the pins are perpendicular to the interfaces. It is therefore unclear which limitation is intended.

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Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.d. 887, 225 USPO 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.d. 937, 214 USPO 761 (CCA 1982); *In re Voges*, 422 F.d. 438, 164 USPO 619 (CCA 1970); and, *In re Thorington*, 418 F.d. 528, 163 USPO 644 (CCA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 110-139 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,200,347. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming what is essentially the same invention only in some cases in slightly different and/or broader language.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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2. Claims 110-114, 116-119, 128 and 132 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyce et al.(6,123,731). Boyce et al. teach a bone-derived implant 20 comprised of alternating layers 22 and 23 of cortical bone demineralized to different degrees. The sources of the bone are preferably allogenic but may also include xenogenic sources. The alternating layers are bound together mechanically and/or with chemical linking. Mechanical engaging features include tongue-and-groove, mortise-and-tenon or mechanical fasteners such as pins, screws or dowels fabricated from natural or synthetic materials. Boyce et al. also teaches that one or more pharmaceutically active agents may be incorporated into the bone-derived implant. These agents, as listed in columns 4 and 5, may include antibiotics and/or growth factors. Finally, Fig. 3 shows the bone-derived implant 20 installed in the vertebral column of a patient.

The limitation requiring the pins to be perpendicular to an interface of the cortical bone portions, is considered to inherently be within the scope of the invention of Boyce et al. Since Boyce et al. suggest the use of pins to mechanically fasten adjacent layers of the graft, without indicating a specific angle, all angles from parallel to perpendicular are inherently included.

Tongue-and-groove engaging features is believed to be representative of an interlocking projection/depression.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 115, 120-127 and 133-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. as applied to claim 110-114 and 117-119 above, and further in view of Gresser et al. (6,241,771). Boyce et al. teach all of the limitations of the present invention except particular dimensions and shapes recited, that the top and bottom surfaces include a plurality of continuous linear protrusions defining a saw-tooth pattern and that the graft includes a through-hole which entirely traverses the graft.

Gresser et al. teach a resorbable interbody spinal fusion device having a top face 11, a bottom face 12, side faces 13, a front end 14 and a back end 15. Top and bottom surfaces 11 and 12 include a plurality of serrations 16 to aid in anchoring the device to surrounding bone. Furthermore, the device includes through holes 18 for the introduction of autologous bone.

It would have been obvious to one of skill in the art at the time of the present invention to have formed teeth on the top and bottom surfaces of the graft of Boyce et al. so as to improve its anchorage into surrounding bone. It would also have been obvious to one of skill in the art at the time of the present invention to have provided through-holes in the Boyce et al. invention to allow for bone ingrowth.

Boyce et al. teach that the height dimension of the parallel block 20 is from about 2 to 20 mm. This places the block in the same size range as the present invention. Boyce et al. teach that different shapes may be used for different applications as exemplified by lines 32-38 of column 5.

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The exact dimensions and shape of the block, including chamfered edges, would have been an obvious matter of design to one of skill in the art at the time of the present invention and dependent upon the intended application.

3. Claims 129-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. as applied to claim 112 and 128 above, and further in view of the following: Boyce et al. teach the use of natural or synthetic materials to form mechanical fasteners such as pins, screws, etc. Making such a fastener of the same material as the block 20 would be obvious in view thereof in order to provide for a consistent material throughout the implant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Thurs. from 7:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. L. Gene Mancene, can be reached on (703) 308-2696.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy
Michael B. Priddy
09/27/2001

Gene Mancene
Gene Mancene
Supervisory Patent Examiner
Group 3700

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.